

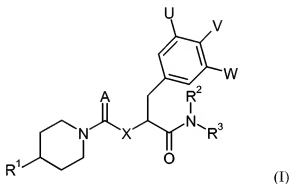
REMARKS / ARGUMENTS

1. Claims Currently Pending

Claims 1-12 were pending. Claims 1-8 have been canceled and new claims 17-78 have been added. Thus, claims 9-12 and 17-78 are now pending.

2. Elected Subject Matter

It is Applicant's understanding (based upon statements made in the Office action mailed June 28, 2006) that the elected invention is regarded by the Office to be compounds of the formula I



wherein R<sup>2</sup> and R<sup>3</sup>, together with the nitrogen atom between them, form a piperidine ring (i.e., Y<sup>1</sup> is a carbon atom).

The claims have been amended so as to delete from their scope compounds that are inconsistent with the election.

3. 35 USC 112, first paragraph, failure to comply with written description requirement

Claims 1-8 and 10-12 once again stand rejected under 35 USC 112, first paragraph, for failure to comply with the written description requirement.

It is believed that the cancellation of claims 1-8 overcomes this basis for rejection.

Notably, claim 9 does not stand rejected under 35 USC 112, first paragraph.

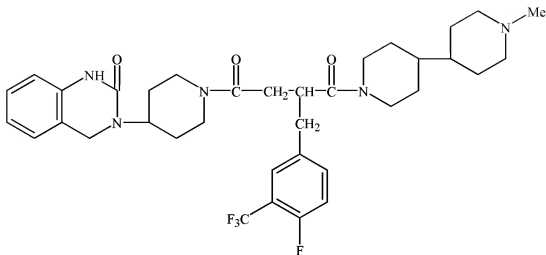
Claim 9 as amended is directed to a subset of the compounds listed in claim 9 as originally filed. These compounds are also explicitly described in the specification as originally filed, in the table that begins on page 27 and ends on page 65. (For the convenience of the Examiner, it should be noted that the table in the specification provides the corresponding chemical structure for each compound named in claim 9.) Thus, claim 9 certainly has antecedent basis in the specification.

The remaining claims all depend from claim 9. Claims 10-12, which formerly depended from claim 1, now depend from claim 9 instead. Claims 17-78 are each directed to a respective one of the compounds listed in claim 9. Claims 10-12 and 17-78 should not be rejected under 35 USC 112, first paragraph because claim 9 should not be so rejected.

4. Rejections Under 35 USC 103

Rejections as Unpatentable Over Rudolf et al., Supplemented with CA 128:257695

Claims 1-12 are rejected under 35 USC 103(a) as being unpatentable over Rudolf et al. (US 6,344,449). As a more specific basis for the rejection, the action asserts that US 6,344,449 discloses the compound having the structure (which for the purposes of this discussion will be called Reference Compound No. 1).

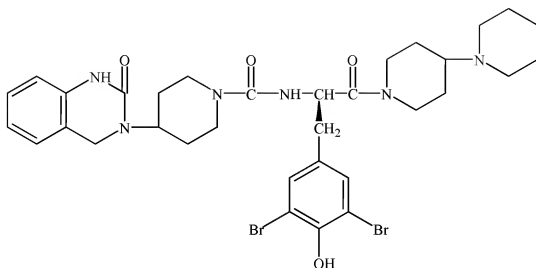


Reference Compound No. 1

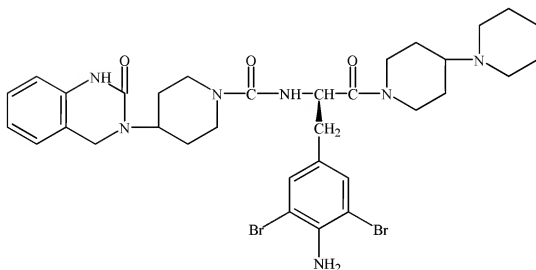
Reference Compound No. 1 is, in fact, disclosed by US 6,344,449. Disregarding stereochemistry, the noted structure corresponds to (R,S)-1-[4-[4-(3,4-Dihydro-2(1H)-oxoquinazolin-3-yl)-1-piperidinyl]-2-[[4-fluor-3-(trifluoromethyl)-phenyl]methyl]-1,4-dioxobutyl]-4-(1-methyl-4-piperidinyl)-piperidine, which is disclosed at column 61, lines 15-18.

The action states that the difference between the formerly pending claims and Reference Compound No.1 is that Reference Compound No. 1 does not have amino or hydroxy substituents on the phenyl ring, as do the compounds of the formerly pending claims.

The action apparently asserts that one of skill in the art would be motivated to replace the fluorine atom of Reference Compound No. 1 with a hydroxyl or amino group because the '449 patent also discloses two other compounds that are members of the same genus (which will be called Reference Compound Nos. 2 and 3) in which the moiety corresponding to V is, respectively, hydroxyl and amino. The structures of Reference Compound Nos. 2 and 3 are provided below.



Reference Compound No. 2

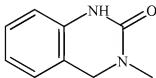


Reference Compound No. 3

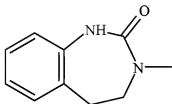
The basis for rejection, as explained above, is not applicable to the claims as now amended.

There is a very notable structural difference between the compounds of the presently amended claims and Reference Compound No. 1. In Reference Compound No. 1 the moiety

which corresponds to  $R^1$  is a 2-oxo-1,3,4-trihydroquinazolin-3-yl group; that is, a group of the following formula:



By way of contrast, in all of the compounds now claimed the moiety corresponding to  $R^1$  is a 2-oxo-1,2,4,5-tetrahydro-1,3-benzodiazepin-3-yl group; that is, a group of the following formula:



It is respectfully urged that the cited prior art does not supply motivation to modify the 2-oxo-1,3,4-trihydroquinazolin-3-yl group of Reference Compound No. 1 to produce an analogous compound that instead has a 2-oxo-1,2,4,5-tetrahydro-1,3-benzodiazepin-3-yl group, as in the compounds now claimed. Thus, the compounds of the present claims are not prima facie structurally obvious over Rudolf et al. (US 6,344,449)/CA 128:257698.

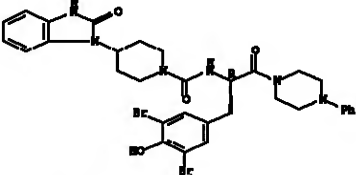
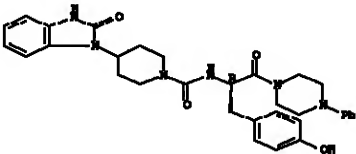
It is urged that this basis for rejection of claim 9 as amended (and all claims depending from claim 9) is overcome by the foregoing.

Rejections as Unpatentable Over Mallee et al. in view of Rudolf et al.

It is urged that the rejection of claims 9-12 under 35 USC 103(a) as unpatentable over Mallee et al. (JOHN J. MALLEE ET AL; Receptor Activity-modifying Protein 1 Determines the Species Selectivity of Non-peptide CGRP Receptor Antagonists; The Journal of Biological Chemistry (4-19-2002) Vol. 277 No. 16 page 14294-14928; The American Society for

Biochemistry and Molecular Biology, Inc./CA 137:304712) in view of Rudolf et al. US 6,344,449 is overcome for the reasons given above with respect to Rudolf taken alone.

The action directs attention to the following two compounds described by Mallee:

<p>RN 204695-47-6                      Mallee Fig. 1                      Compound 1</p>	
<p>RN 472966-25-9                      Mallee Fig. 1                      Compound 2</p>	

The combination with Mallee does not supply motivation to modify the 2-oxo-1,3,4-trihydroquinazolin-3-yl group of Reference Compound No. 1 (of the '449 reference) to produce an analogous compound that instead has a 2-oxo-1,2,4,5-tetrahydro-1,3-benzodiazepin-3-yl group, as in the compounds now claimed. In the two cited compounds of Mallee et al. the moiety that corresponds to R<sup>1</sup> is a 2-oxo-3-hydrobenzimidazol-1-yl group, and not a 2-oxo-1,2,4,5-tetrahydro-1,3-benzodiazepin-3-yl group, as in the compounds now claimed. Thus, the compounds of the present claims are not prima facie structurally obvious over Rudolf et al. (US 6,344,449)/CA 128:257698 combined with Mallee.

5. Obviousness-type Double Patenting

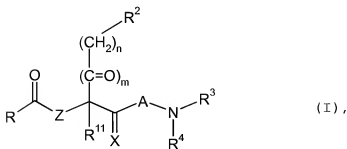
Rejection of Claims 1-12 as Unpatentable Over Rudolf et al., Supplemented with CA 128:257695

It is urged that claims 9-12 are not properly rejected on the ground of nonstatutory obviousness-type double patenting, as unpatentable over Rudolf et al., US 6,344,449, supplemented with CA 128:257695. If the compounds of the invention as now claimed are not prima facie obvious over Rudolf as has been demonstrated above, there is no valid basis for obviousness-type double patenting. For the same reason, new claims 17-78 should not be subject to such rejection.

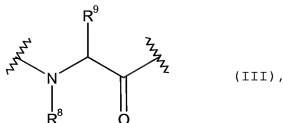
Provisional Rejection of Claims 1-12 as Unpatentable Over Co-Pending 10/835,495 in view of CA 128:257695

It is urged that the provisional rejection of claims 9-12 on the ground of nonstatutory obviousness-type double patenting, as unpatentable over co-pending 10/835,495 in view of CA 128:257695 is improper and should be withdrawn in that the pending claims are not prima facie obvious over claims 15-19 of co-pending 10/835,495. For the same reason, new claims 17-78 should not be subject to such rejection.

Claims 15-19 of co-pending application 10/835,495 are directed to compounds of the formula I



wherein the moiety A is a divalent group of formula



that is linked to the group  $\text{-NR}^3\text{R}^4$  of formula (I) via the carbonyl group.

The compounds of the claims in the present application lack a structural feature that corresponds to the moiety A of the co-pending application. It has not been demonstrated that one of ordinary skill in the art would be motivated to modify the compounds of claims 15-19 of co-pending application 10/835,495, by removal of this structural feature, so as arrive at the compounds presently claims. For this reason, it has not been demonstrated that the compounds of the present claims are prima facie structurally obvious over claims 15-19 of the '495 patent and therefore not patentably distinct. Accordingly, it is respectfully asserted that a prima facie case of non-statutory double patenting has not been established by the Office.

Provisional Rejection of Claims 1-12 as Unpatentable Over Co-Pending SN 11/757,743 (continuation of SN 10/685,921 in view of US 6,344,449)

Claims 9-12 of the present application are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of co-pending 11/757,743 in view of US 6,344,449. Presumably this ground of rejection would be applicable to new claims 17-78.

Applicant stands ready to overcome such rejection, when it becomes non-provisional, with a terminal disclaimer.



Provisional Rejection of Claims 1-12 as Unpatentable Over Co-Pending 10/755,593,  
11/107,052 and 11/107,195, each in view of US 6,344,449

Claims 9-12 of the present application are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of co-pending 10/775,593 in view of US 6,344,449. Presumably this ground of rejection would be applicable to new claims 17-78. This provisional rejection is traversed for the following reason.

It is respectfully asserted that, in view of the foregoing amendments and arguments, no grounds for rejection remain in the present application, aside from the present obviousness-type double patenting rejections.

Reference is made to the discussion of double patenting rejections in MPEP Section 804, and in particular to the discussion respecting provisional obviousness-type double patenting (ODP) rejections between copending applications having a common owner or assignee.

In this regard, it should be noted that the present application and the three copending applications cited are co-owned.

MPEP Section 804 states as follows:

If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer.

As shown by the table below, the present application is earlier filed than copending 10/755,593, 11/107,052 and 11/107,195. Accordingly, and in view of the instruction given by MPEP 804, the Office should withdraw the ODP rejection to the extent that it is based upon these three co-pending applications.

Application	U.S. Filing or 371(c) Date
10/687,262 (present application)	10/16/2003
10/755,593 (copending)	1/12/2004
11/107052 (copending)	4/15/2005
11/107195 (copending)	4/15/2005

Provisional Rejection of Claims 1-12 as Unpatentable Over Claim 1 of SN 11/301,422 or Claims 1-2 of SN 11/301,446

Claims 1-12 of the present application are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of SN 11/301,422 or Claims 1-2 of SN 11/301,446. This provisional rejection is traversed for the following reasons.

SN 11/301,422 is abandoned. However, SN 11/774,995 is pending.

SN 11/301,446 is abandoned. However, SN 11/744,980 is pending.

It is respectfully asserted that, in view of the foregoing amendments and arguments, no grounds for rejection remain in the present application, aside from the present obviousness-type double patenting rejections.

Reference is made to the discussion of double patenting rejections in MPEP Section 804, and in particular to the discussion respecting provisional obviousness-type double patenting (ODP) rejections between copending applications having a common owner or assignee.

In this regard, it should be noted that the present application and the two copending applications cited are co-owned.

MPEP Section 804 states as follows:

If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should

withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer.

As shown by the table below, the present application is earlier filed than copending 11/744,995 and 11/744,980. Accordingly, and in view of the instruction given by MPEP 804, the Office should withdraw the ODP rejection to the extent that it is based upon these three co-pending applications.

Application	U.S. Filing or 371(c) Date
10/687,262 (present application)	10/16/2003
11/744,995 (copending)	12/13/2005
11/744,980 (copending)	12/13/2005

Conclusion:

It is respectfully urged that the above amendments and arguments obviate all stated grounds for rejection and that the claims and the application as a whole are now in condition for allowance.

Respectfully submitted,

/Alan Stempel/  
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